DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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January 2, 2015

Orthofix, Incorporated
Ms. Jacki Geren
Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K141186
Trade/Device Name: Firebird Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, OSH, MNI, MNH, KWP
Dated: October 31, 2014
Received: November 6, 2014

Dear Ms. Geren:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141186

Device Name
Firebird Spinal Fixation System

Indications for Use *(Describe)*
The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle, and non pedicle fixation (T1 – S2/ Ilium). Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:
a) Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
b) Spondylolisthesis;
c) Trauma (i.e., fracture or dislocation);
d) Spinal stenosis;
e) Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
f) Tumors;
g) Pseudoarthrosis, and
h) Failed previous fusion
When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The Firebird Spinal Fixation System components are used with certain components of the Orthofix Spinal Fixation System, including rods, rod connectors and cross-connectors.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Firebird Spinal Fixation System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Name:	Orthofix Inc.
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Email:	jackigeren@orthofix.com
Registration Number:	3008524126
Contact Person:	Jacki Geren Regulatory Affairs Specialist
Date Prepared:	May 6, 2014

Name of Device

Trade Name/Proprietary Name:	Firebird Spinal Fixation System
Common Name:	Spinal Fixation System
Product Code:	NKB; OSH; KWP; MNH; MNI
Regulatory Classification:	21 CFR §888.3070 Pedicle screw spinal system (Class III)
Review Panel:	Orthopedic Device Panel
Predicate Devices:	Orthofix Firebird Spinal Fixation System – K130932 (primary predicate) LDR Spine USA SpineTune TL System – K120760 (additional predicate) No reference devices were used in this submission
Reason for 510(k) Submission:	Modification to all straight titanium alloy (Ti-6AL-4V ELI) rods to place a line longitudinally along the length of the rod to provide better identification of induced curvature.
Device Description:	The Firebird Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body and ilium by means of screw or hook fixation to the non-cervical spine. The Firebird Spinal Fixation System consists of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks and iliac connectors.

Intended Use / Indications for Use:

The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle, and non pedicle fixation (T1 – S2/Ilium). Pedicle screw fixation is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

a) Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies);
b) Spondylolisthesis;
c) Trauma (i.e., fracture or dislocation);
d) Spinal stenosis;
e) Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis);
f) Tumors;
g) Pseudoarthrosis, and
h) Failed previous fusion

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation System is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The Firebird Spinal Fixation System components are used with certain components of the Orthofix Spinal Fixation System, including rods, rod connectors and cross-connectors.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Firebird Spinal Fixation System for pediatric use is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Summary of Technological Characteristics of the Device Compared to the Selected Predicate Device

Characteristics	Firebird Spinal Fixation System (Subject Device)	Predicate Device: Firebird Spinal Fixation System (K130932)	Predicate Device: LDR Spine USA SpineTune TL System (K120760)
Device Name	Firebird Spinal Fixation System	Firebird Spinal Fixation System (K130932)	SpineTune TL System (K120760)
Method of Fixation	Non-Cervical Fixation	Non-Cervical Fixation	Non-Cervical Fixation
Implantation	Posterior Approach	Posterior Approach	Posterior Approach
Design	This system allows a surgeon to build a spinal implant construct	This system allows a surgeon to build a spinal implant construct	This system allows a surgeon to build a spinal implant construct
Material	Titanium alloy (Ti-6AL-4V ELI)	Titanium Alloy (Ti-6AL-4V ELI)	Titanium alloy
Longitudinal Line on Rods	Yes	No	Yes

PERFORMANCE DATA - Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

Characteristics	Standard / Test / FDA Guidance
Static Torsion Test	N/A No change from the predicate device
Static Axial Compression Bending Test	N/A No change from the predicate device
Dynamic Axial Compression Bending Test	ASTM F1717-14
Axial Rod Gripping Test	ASTM F1798-13

Performance Data Summary

Mechanical testing for the subject Firebird Spinal Fixation System lined rods were conducted in accordance with ASTM F1717-14 *Standard Test Method for Static and Fatigue for Spinal Implant Constructs in a Vertebrectomy Model* and ASTM 1798-13 *Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants*. Test results demonstrated that the subject lined rods are substantially equivalent to the predicate device Firebird Spinal Fixation System (K130932) which has the same intended use, similar indications, technological characteristics, and principles of operations

Basis of Substantial Equivalence

The subject Firebird Spinal Fixation System straight titanium alloy (Ti-6AL-4V ELI) lined rods are substantially equivalent to the predicate devices based on indications for use, intended use, design, materials and function and mechanical performance.